UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,039	12/12/2005	Reinhard Ebner	689290-226	7587

7590 11/16/2007

Alan J Grant
Carella Byrne, Bain Gilfillan
Cecchi Stewart & Olstein
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER	
YAO, LEI	
ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,039	EBNER ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, drawn to in vitro process for identifying an agent that modulates the activity of a cancer-related gene comprising: (a) contacting a compound with a cell containing a gene (b) detecting a difference in expression of said gene of SEQ ID NO:1, 2, 3 or 4, thereby identifying an agent that modulates the activity of a cancer-related gene.

Group 2, claim(s) 8, drawn to in vivo process for identifying an agent comprising administering to an animal exhibiting a cancer condition an effective amount of an agent and detecting a decrease in the cancer condition.

Group 3, claim(s) 9 and 10, drawn to a process for determining the cancerous status of a cell, comprising determining an increase in the level of expression in said cell of a gene, wherein an elevated expression relative to a known non-cancerous cell indicates a cancerous state.

Group 4, claim(s) 11,12, 27, and 28 drawn to an isolated polypeptide or immunogenic composition comprising an amino acid sequence homologous to an amino acid sequence selected from the group consisting of SEQ ID NO: 5 and 6 or fragments.

Group 5, claim(s) 13-23, drawn to an antibody or antibody conjugate to protein of SEQ ID NO: 5 or 6.

Group 6, claim(s) 24-26, 29-31, drawn to a process for treating cancer comprising contacting a cancerous cell in vivo with an agent (antibody) having activity against an expression product (peptide) encoded by a gene sequence selected from the group consisting of SEQ ID NO: 1, 2, 3 and 4.

Group 7, claim(s) 32-35, drawn to drawn to process for treating cancer or protecting cancer comprising administering the animal or a cancerous cell with an agent identified in claim 8 (not antibody).

Group 8, claim(s) 36, drawn to a method for producing test data with respect to the gene modulating activity of a compound comprising: contacting a compound with a cell containing a polynucleotide comprising a nucleotide sequence corresponding to a gene whose expression, determining a change in expression of polynucleotides as a result of said contacting, and producing test data.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a

process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as groups do not related to a single general invention concept because they lack the same or corresponding special technical feature. The technical feature of group 1 and 4-6 drawn to DNA, protein, antibody and process of using to treat a disease or identify a compound for modulating a disease associated with expression of the gene product which is shown by Nagase et al (DNA Res, vol 7, page 143-150, 2000) to lack novelty or inventive step. The Nagase et al teach that a DNA that is 99.7% identical to SEQ ID NO:2 (see sequence search result attached) and its encoding peptide. Therefore, the inventions, peptide and method of using its coding DNA, do not make a contribution over the prior art. Because the peptide and its coding DNA is known or obvious to use for making an antibody or us for detecting or treating a disease in the art, the technical feature of the Group 4 is not a special technical feature, the unity of inventions (Group 1 and 4-6) is lacking.

In addition, according to PCT rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The groups 1-3 and 6-8 are directed to methods of treating a disease or identifying an agent to modulate the gene product but each group has ad different special technical feature not sheared by the remaining groups. Group I is directed to in vitro process for identifying an agent that modulates the activity which has the special technical feature of in vitro inventive step of identifying a modulator, Not shared by any of the remaining groups. Group 2 is directed to in vivo process for identifying an agent that modulates the activity, which has the special technical feature of in vivo administering the agent, not shared by any of the remaining groups. Group 3 is directed to process for determining a cancer cells, which has the special technical feature of cancer cells, not shared by any of the remaining groups. Group 6-8 are directed to process for treating a

disease with antibody, non antibody, or collecting data in computer, each has the special technical feature respectively above, not sheared by any of the remaining groups.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

A. Elect ONE sequence from SEQ ID NO:1-6.

B. Elect ONE cytotoxic agent listed in 18, 19, 20, 21, 22, or 23.

Applicants elect any group from 1-8 above, elect one single sequence from SEQ ID NO: 1, 2, 3, 4, 5 or 6 listed in A is required for examination. The election of any SEQ ID NO should correspond with the product or the method of using in the elected group 1-8. For example, elect group 4, an isolated peptide, further elect SEQ ID NO: 5 (amino acid sequence) for examination.

In the event that applicant elects invention group 5 or 6 applicant is required under 35 U.S.C. 121 to elect a single disclosed species from B for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, elect group 5, antibody or conjugate, elect species taxol listed in claim 18 for examination.

It is noted if applicants amend to the claims in any elected invention by adding more species listed above, which are not originally recited in the claims, applicant is required to elect ONE species along with the elected invention in the response to the restriction requirement.

The species are independent or distinct because they are structurally and functionally distinctive product. Prior art, which teaches one species, would not necessarily be applicable to the method of using another or all the species. Searching the all the species in the method together would impose serious search burden.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600